TGF-β3), the defining feature of the claims is that there is sufficient TGF-β3 to have an anti-fibrotic effect.

In the Amendment filed June 4, 1999, the claims were revised to read "an amount of transforming growth factor consisting essentially of TGF-β3". As the Examiner appreciates, "consisting essentially of" excludes ingredients that would materially affect the basic and novel characteristics of the invention -- in the present case, the anti-fibrotic effect of TGF-β3. No further revision of the claims should be necessary and thus no further revision is offered here (see comments that follow).

Claims 56-71 remain rejected under 35 USC 112, first paragraph, as allegedly being non-enabled. Withdrawal of the rejection is submitted to be in order for the reasons that follow.

The rejection is based on an alleged lack of enablement of the "anti-fibrotic agents". The precise nature of such agents, however, is not critical to the claimed invention. All that is required is that the agent be "anti-fibrotic".

The Examiner's concerns regarding the functional language used to define the "agents" may have merit if the claims were drawn to such agents, or compositions comprising same. However, the functional recitations are again submitted to be entirely appropriate in the context of the present method claims.

With respect to (C) and (D) of item (5) of the Action, attention is again directed to the fact that oligonucleotides and ribozymes represent well known agents that may be used to inhibit the activity or production of a target protein. A skilled person would be familiar with these kinds of agents and it would only require routine effort to produce the agents for use according to the method of the invention. Accordingly, evidence of the type indicated by the Examiner should not be necessary.

The transfection of cells and the effects of nucleases (item 5(C)) represent developmental issues that do not detract from the usefulness of oligonucleotides and ribozymes. While the Example of the subject specification relates to neutralizing antibodies, the Examiner is reminded that it is not necessary to provide substantiating data for every alternative covered by a claim. In this respect, ribozymes and oligonucleotides represent well known alternatives to neutralizing antibodies. Applicants, therefore, again submit that they should be entitled to protection for these agents in the context of the present method claims.

As for item (5(D)), the Examiner is reminded that the claims require the inhibition of fibrosis (claim 56) or reduction of scarring (claim 64) as a result of the provision of a sufficient amount of TGF-β_3. Accordingly, no need is seen for a limitation

to the effect that the agent does not significantly affect TGF-β3, or for evidence of the type indicated by the Examiner.

Reconsideration is requested.

Claims 56, 62, 63, 64, 70 and 71 stand rejected under 35 USC 103 as allegedly being obvious over Cerletti et al. Withdrawal of the rejection is believed to be in order in view of the prior claim revisions, introduced for purposes of clarity, which revisions result in the **exclusion** of ingredients that would materially affect the basic and novel characteristics of the invention.

That is, the present language clearly excludes the presence of amounts of TGF-β1 and TGF-β2 that would materially affect the "inhibition of fibrosis" or "reduction in scarring" provided by TGF-β3. Nothing in Cerletti would have suggested the critically of TGF-β3 in the context of the present methods and exclusion of amounts of, for example, TGF-β1, and TGF-β2 that would materially affect that method. Accordingly, reconsideration is requested.

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

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